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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,566	07/28/2000	Jonathan L. Goodwin	ATA-286	2331
959	7590	01/14/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			BUI, VY Q	
			ART UNIT	PAPER NUMBER
			3731	
			DATE MAILED: 01/14/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/627,566

Applicant(s)

GOODWIN ET AL.

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on telephone interview on 12/3/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-4 and 6-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 18.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS et al (5,749,880) in view of KOWLIGI et al (5,466,509).

As to claims 1 and 4, BANAS (Fig. 7, 7B; col. 18, lines 51-60) discloses a stent-graft implant 100 comprising stent 116 sandwiched between inner cover 112 and outer cover 114 of expanded PTFE having IND in a range from 0.1-100 microns, inner cover 112 and outer cover 114 (each of a predetermined thickness) extend substantially along the entire length of the stent 116. BANAS does not disclose the expanded PTFE having IND of more than 100 microns. However, KOWLIGI (col. 2, lines 4-7; claim 1) discloses an ePTFE graft material having IND in the range from 10-200 microns or greater than 100 microns to provide a graft material having high porosity affecting an incorporation of tissue to the graft after surgery (KOWLIGI: col. 1, lines 25-28; col. 2, lines 4-7). In view of KOWLIGI teaching, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide ePTFE of IND greater than 100 microns for the BANAS's inner cover 112 or outer cover 114 as this configuration of the inner and outer covers would form a graft having high porosity to affect an incorporation of

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tissue to the graft after surgery. The fact that the Applicants use the cover/graft having IND >100 microns in the present stent-graft device as claimed for a different purpose (to reduce a deployment pressure necessary to expand the stent) from KOWGILI (to provide a high porosity for the graft) does not alter the conclusion that the cover/graft as claimed would be prima facie obvious from the cover/graft combined by BANAS and KOGILI references." In re Lintner, 173 USPQ 560. In addition, even though BANAS and KOWGILI do not disclose graft material having IND of greater 100 microns to reduce a deployment pressure necessary to expand the stent-graft combination to less than 10 atmospheres, since every structural limitation as recited in the claims is included by the combination stent-graft of BANAS and KOWGILI (stent and cover/graft having IND greater than 100 microns), inherently, the stent-graft combination of BANAS and KOWGILI would require a reduced deployment pressure (less than 10 atmospheres for example).

As to claims 6 and 9, KOWGILI (Table in col. 3 shows wall thickness of 0.64 mm or about 0.026" >0.008".

2. Claims 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS and KOWGILI as applied to claims 1 and 6 above, and further in view of MYERS et al. (5,735,892).

BANAS and KOWGILI discloses substantially all structural limitations of the claimed invention, except for inner cover 112 is folded over stent 116. However, folding an inner cover over an outer surface of a stent to form an outer cover is well known in the art. For example, MYERS (Fig. 8) discloses inner cover 83 folded over the outer surface of stent 10 to form outer cover 85.

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3. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS and KOWGILI as applied to claims 1 and 6 above, and further in view of MYERS et al. (5,735,892).

As to claims 3 and 8, in addition to BANAS and KOWGILI, MYERS (Fig. 8) shows inner cover 83 folded over the outer surface of stent 10 to form outer cover 85. BANAS and KOWGILI do not show the second portion of the inner cover 83 folded over the first portion of the inner cover 83. Naturally, applying multiple folding layers over an object would provide extra securement between the folding layers and the object. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to fold the second portion of the inner cover 83 over the first portion of the inner cover 83 as this configuration would provide extra securement between MYERS stent 10 and graft 83. Beside the benefit of providing an extra securement between MYERS stent 10 and graft 83 as discussed above, the second folding of the second portion of the graft 83 does not appear to provide any significant improvement for the device's performance and therefore would not be considered as an significant novel feature of the instant application over the reference.

### ***Response to the Applicants Request***

In the telephone interview on 12/3/2003, the applicants attorney, Mr. RIKKERS, requested the examiner to reconsider the finality of the last Office action. The examiner expressed concern that the DAVILA reference (US Pat. 6,296,661) was applied in the

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first Office action (paper # 5) mailed 12/06/2001, but only until 6/30/2003 the applicants filed the affidavit under CFR 1.131.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is (703) 306-1382 and whose email address is vy.bui@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano, can be reached at (703) 308-2496. The fax number for this Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858



VQB

12/04/2003.